UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge Honorable Joel Schneider, Magistrate Judge

REPLY MEMORANDUM OF LAW IN SUPPORT OF RULE 12 MOTION TO DISMISS SUBMITTED ON BEHALF OF ALL PHARMACY DEFENDANTS

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Despite more than one hundred pages of consolidated briefing, Plaintiffs cite no case holding that a pharmacy defendant can be held liable for dispensing, pursuant to physicians' orders, an FDA-approved prescription drug with a latent defect that is unknown to the pharmacy. This failure underscores what Plaintiffs prefer to ignore: the baseless and unprecedented nature of the strict liability and warranty liability Plaintiffs seek to impose on the Pharmacies in this case.

Plaintiffs advance several additional claims, including fraud and negligence, predicated on supposed but unsupported conduct of the Pharmacies (or on lumping all "Defendants," as alleged in the Master Complaints, together). Those claims fail for the reasons set forth in the Defendants' opening briefs, which Plaintiffs have not meaningfully rebutted in their opposition. Plaintiffs still have failed to identify any factual or legal basis for asserting that the Pharmacies knew of, should have known of, or should have tested drugs to identify any latent defects. Moreover, Plaintiffs' assertion that the Pharmacies should have done more is preempted by the Drug Supply Chain Security Act (the "Act" or "Drug Security Act"). For these reasons, and those set forth in the Defendants' opening briefs,[1] the Court should dismiss all claims against the Pharmacy Defendants.

[1] Plaintiffs assert that the Pharmacies "do not challenge any standing" (Dkt. 577 ("Opp.") at 32) and suggest the Pharmacies did not join the other Defendants' arguments. They are wrong: the Pharmacies expressly adopted all of the arguments of the Manufacturer and Wholesaler Defendants, including "lack of standing." (Dkt. 523-1 ("Pharmacy Br.") at 4.) Similarly, the Pharmacies adopt

I. Plaintiffs' claims fail as a matter of state substantive law.

In their opening brief, the Pharmacies explained why Plaintiffs cannot state express-warranty, unjust-enrichment/disgorgement, or consumer-protection claims against the Pharmacies. (*See* Pharmacy Br. at 18–19, 26–29). As Plaintiffs offer no response, those claims should be dismissed. *See Ali v. D.C. Court Servs.*, 538 F. Supp. 2d 157, 161 (D.D.C. 2008) ("If a plaintiff . . . files an opposition to a motion to dismiss addressing only certain arguments raised by the defendant, a court may treat those arguments that the plaintiff failed to address as conceded."). That leaves Plaintiffs' strict and implied warranty theories of liability, which no court has recognized against a pharmacy, and Plaintiffs' negligence or fraud-based theories of liability, which fail for a complete lack of supporting allegations.[2]

A. Pharmacies are not subject to strict or warranty liability.

The Pharmacies offered persuasive, case-law-based arguments to establish that Plaintiffs' faultless liability claims against the Pharmacies fail across jurisdictions. In response, *Plaintiffs fail to cite a single case holding a pharmacy liable for filling a prescription that contained a latent defect*. Instead, Plaintiffs

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and incorporate by reference the arguments in the reply briefs submitted contemporaneously by the other Defendants.

[2] Because Plaintiffs relegate their only detailed attempt to rebut the Pharmacies' Rule 12 arguments to pages 99–103 of their opposition—eight pages beyond their page limit—this Court should decline to even consider those pages.

claim that "[m]any states have not addressed this issue at all, such as Alaska, Hawaii, Maine, New Hampshire, and South Dakota." (Opp. at 102.) But that misses the point. This Court should not subject the Pharmacies to participation in this multidistrict litigation simply because Alaska's or South Dakota's courts have not yet had an opportunity to address this issue and to join other courts who have rejected faultless pharmacy liability. No court has ever done what Plaintiffs are now asking this Court to do.

In fact, many states have innocent seller laws that explicitly preclude the kind of faultless liability that Plaintiffs seek to impose on the Pharmacies here. Plaintiffs' lone rebuttal to those laws is to suggest deferring the adjudication of this issue until after expensive discovery. (Opp. at 105.) That makes no sense, particularly where, as here, the manufacturers have been identified, are named in these suits, and are vigorously defending against Plaintiffs' claims. Plaintiffs have not adequately pleaded any exception to the innocent seller statutes, such as substantial control or constructive knowledge. Further, even if some exception to an innocent seller law applied, the exception would apply only if a pharmacy took some action that made it culpable, *not innocent*, under the statute; it would not be because some faultless liability standard applied.[3]

[3] The Pharmacies do not "sell" valsartan any more than a hospital "sells" a medical device it implants. Regardless, Plaintiffs' strict liability and warranty claims seek to impose liability on the Pharmacies for "selling" valsartan, and these statutes—

Plaintiffs' attempts to sidestep the legion of cases rejecting pharmacy strict liability all fail. Plaintiffs cite five cases referencing the *idea* of strict liability without a single discussion of pharmacies.[4] (Opp. at 99.) Next, Plaintiffs cite an unpublished memorandum from a Connecticut state trial court involving a prescription misfill. (Opp. at 100–101, citing *Stanko v. Bader*, No. CV030193669, 2003 WL 22413376, at *1 (Conn. Sup. Ct. Oct. 7, 2003).) Of course, this is not a misfill case, and no Connecticut appellate court has accepted the idea that a pharmacy's negligent provision of the wrong medication states a product-liability or warranty claim, and multiple Connecticut trial courts have rejected that idea.[5]

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above and beyond pharmacies' common-law protections—provide additional reasons to dismiss the Pharmacies.

[4] Even these cases are inapt. *Promaulayko* determined, as between two blameless sellers, that the one closer to the manufacturer had to indemnify the further downstream defendant. *Livingston* did not apply strict products liability to the owner/operator of a hotel. *Peterson* declined to impose strict liability on a used car dealer. *Ritter* cited numerous California cases on strict liability, which rejects the doctrine for claims against pharmacies. And *Dippel* simply adopted § 402A of the Restatement but also noted that sellers are not insurers. *See Promaulayko v. Johns Manville Sales Corp.*, 562 A.2d 202, 207–08 (N.J. 1989); *Livingston v. Begay*, 652 P.2d 734, 738–39 (N.M. 1982); *Peterson v. Lou Bachrodt Chevrolet Co.*, 329 N.E.2d 785, 787 (Ill. 1975); *Ritter v. Narragansett Elec. Co.*, 283 A.2d 255, 262 (R.I. 1971); *Dippel v. Sciano*, 155 N.W.2d 55, 63–64 (Wis. 1967).

[5] *See, e.g.*, *Henderson v. CVS Pharm., Inc.*, No. CV085017128, 2008 WL 3916444, at *4 (Conn. Sup. Ct. July 31, 2008) ("A pharmacist . . . is considered, under Connecticut statutes, to be a licensed health care provider providing professional services and, therefore, cannot be a product seller[.]"); *Altieri v. CVS Pharm., Inc.,* No. X06CV020171626S, 2002 WL 31898323, at *4 (Conn. Sup. Ct. Dec. 13, 2002) (dispensing prescriptions is a service, and plaintiffs' claims for a misfill

Plaintiffs then cite two cases that explicitly *reject* the idea of strict liability for pharmacies. (Opp. at 100–01, citing *Kohl v. Am. Home Prod. Corp.*, 78 F. Supp. 2d 885 (W.D. Ark. 1999), and *Murphy v. E.R. Squibb & Sons, Inc.*, 710 P.2d 247 (Cal. 1985).) *Murphy* further noted that pharmacies cannot dispense a prescription "except by order of the doctor" and thus are "providing a service to the doctor and acting as an extension of the doctor in the same sense as a technician who takes an X-ray or analyzes a blood sample on a doctor's order." 710 P.2d at 251; *see also Garza v. Endo Pharm.*, No. CV 12-1585-CAS OPx, 2012 WL 5267897, at *2 (C.D. Cal. Oct. 24, 2012) ("Because under California law pharmacies primarily provide a service, not a product, a breach of warranty claim does not lie.").

"describe what is clearly a negligence claim, which is properly dealt with in the counts asserting negligence"). In a footnote, Plaintiffs cite another unpublished Connecticut trial court decision, *Ramos v. Rite Aid Corp.*, No. CV106008649, 2010 WL 4277612, at *1 (Conn. Sup. Ct. Oct. 7, 2010), for the proposition that restrictions on pharmacy strict liability are limited to failure-to-warn claims. But in that case—yet another misfill decision—the court struck the product liability claims against the pharmacy and left only the negligence claims. (Opp. at 102.) Plaintiffs similarly claim that the Pharmacies' chart of case law is "incomplete and inaccurate," but they fail to identify *any* specific error or provide case law of their own to demonstrate a counter proposition to any point therein. (Opp. at 103.) To be sure, the chart provides *general* citations to cases involving service providers, such as *Burnett v. Covell*, 191 P.3d 985, 988 (Alaska 2008), or *Birmingham v. Fodor's Travel Publ'ns, Inc.*, 833 P.2d 70, 79 (Haw. 1992), but this reflects only that courts in those states have not yet needed to address pharmacy strict liability.

Both *Murphy* and *Kohl*, like other similar decisions, focus on the problematic nature of imposing strict liability on pharmacies that do not control the manufacturing process of an FDA-approved drug. "If pharmacies were held strictly liable for the drugs they dispense, some of them, to avoid liability, might restrict availability by refusing to dispense drugs which pose even a potentially remote risk of harm, although such medications may be essential to the health or even the survival of patients." *Murphy*, 710 P.2d at 253. "[A]s to preventing the circulation of defective products, it would ill-serve the needs of the public to impose a duty on pharmacists under which, to avoid potential liability, they might refuse to fill prescriptions[.]" *Kohl*, 78 F. Supp. 2d 885, 895 (*quoting Coyle v. Richardson-Merrell, Inc.*, 584 A.2d 1383, 1387 (Pa. 1991)). In other words, imposing no-fault liability on pharmacies for defects they can neither control nor detect works a significant potential cost: a reduction in the supply of essential, lifesaving FDA-approved drugs.

As to warranty claims specifically, faced with insurmountable case law confirming that pharmacies are not merchants who warrant goods, Plaintiffs respond by suggesting that this case law somehow applies only to design defect claims. (Opp. at 57–58.) This attempt at line drawing gets them nowhere.

First, even under the line Plaintiffs draw, the cases preclude pharmacy warranty liability because Plaintiffs themselves assert design defect claims. (Opp.

at 92 (claiming that the Manufacturer Defendants "chose to bring new designs to market that contained nitrosamines").) Even under Plaintiffs' theory, the case law rejects their claims.

Second, the only case Plaintiffs muster in support of this novel claim is *Fagan v. AmerisourceBergen Corp.*, 356 F. Supp. 2d 198 (E.D.N.Y. 2004), which involved a *patent*, not latent, defect. There, the defendant pharmacy allegedly shipped a counterfeit drug to the plaintiff *after* its particular lot number had been publicly identified as being counterfeit. *Id.* at 204. The plaintiffs there also alleged that the pharmacy could have identified the counterfeit drug even before it had been publicly identified as such by simply inspecting the label, as the counterfeit drug contained different labeling than the drug of the FDA-approved manufacturer. *Id.* at 213. The facts here are not even close to *Fagan*'s. This case involves a *latent* defect, an alleged impurity in valsartan that even the FDA agreed was difficult to detect. (*See* Pharmacy Br. at 21.) Plaintiffs have not, and cannot, identify any patent defect in the valsartan at issue that would have enabled the Pharmacies to identify the drug as mislabeled or adulterated.

Moreover, the reasoning of the Pharmacies' case law precludes Plaintiffs' attempted distinction. Those cases make clear that the relevant question is not the type of defect, but the conduct of the pharmacies—specifically, whether they performed their drug-dispensing roles appropriately. To put it in warranty terms,

the most that a pharmacy could ever warrant is that it dispensed a drug in the right quantities with the correct labeling, and as received from an FDA-approved supplier with the transaction information required under the Drug Security Act. The pharmacy in *Fagan* could not satisfy that warranty because the counterfeit drug had the wrong label and, moreover, was distributed before the Drug Security Act required transaction statements. Here, Plaintiffs plead nothing to suggest the Pharmacies did anything other than dispense a drug sourced from FDA-approved suppliers. Plaintiffs offer no reason for the Court to depart from the uniform rule rejecting pharmacy warranty liability under these circumstances.

Finally, Plaintiffs offer *only one* rationale for alleging strict and warranty liability against the Pharmacies in this litigation: that the pharmacies have, and can, obtain insurance or indemnification to shift the risk and liabilities of dispensed drugs containing a latent defect. (Opp. at 67, 101.) But courts uniformly reject risk spreading when it is the *only* rationale underlying strict liability, reasoning that "it was never the intention of the drafters of the doctrine [of strict liability] to . . . impose *absolute* liability." *Anderson v. Owens-Corning Fiberglas Corp.*, 810 P.2d 549, 559 (Cal. 1991). "To assign liability for no reason other than the ability to pay damages is inconsistent with our jurisprudence." *Cafazzo*, 668 A.2d at 526; *see also Coyle,* 584 A.2d at 1387 (finding "[r]eliance on cost-shifting as the only factor to be considered in whether a given party should be exposed to liability"

insufficient to support liability because it "would result in absolute liability rather than strict liability"). Courts will not "write a judicial ticket" for insurance:

> Another problem with relying exclusively upon the doctrine of loss spreading to justify the imposition of liability without fault is that the same reasoning could be used to impose strict liability in *any* situation in which the defendant is in a superior position economically to bear or distribute the loss suffered by the plaintiff. . . . Spreading the cost of injury throughout society amounts to no more than a judicially imposed insurance system.

Peterson v. Superior Court, 899 P.2d 905, 919 (Cal. 1995) (citation omitted); *see also Winters v. Alza Corp.*, 690 F. Supp. 2d 350, 356 (S.D.N.Y. 2010) (asking "pharmacies [to] ensure the complete safety of any product that they dispense . . . is not only wrong as a matter of law, but it would also impose a duty on pharmacists that is grossly disproportional to their limited degree of expertise"). As Plaintiffs themselves recognize (*see* Opp. at 67 n.20), many states extended the law to allow for strict or expanded warranty liability in the first place precisely to avoid the "wastefulness and uncertainty of a series of warranty actions carrying liability back through retailer, jobber and wholesaler to the original maker[.]" *Middleton v. United Aircraft Corp.*, 204 F. Supp. 856, 859 (S.D.N.Y. 1960) (*quoting* Prosser on Torts (2d ed.) at 506–07)). Here, the only point of including the Pharmacies in the litigation is to subject the Pharmacies to more onerous discovery and increase defense and indemnity costs. But even an understandable desire to ensure that injured consumers receive compensation from someone

cannot justify allowing Plaintiffs' claims against the Pharmacies to proceed, given the legal deficiencies of those claims. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 625 (2011) (acknowledging "the unfortunate hand that federal drug regulation has dealt" consumers, but denying their claims). Plaintiffs have not cited a single court that has considered this issue and come out their way. Nor have they offered any reason why this Court, especially in light of the authorities holding otherwise, should be the first.

B. Plaintiffs have not pleaded fault-based claims against the Pharmacies.

1. Plaintiffs' inadequate group pleading deprives the Pharmacies of fair notice of the claims against them.

Though Plaintiffs deny that their Complaints are shotgun pleadings (Opp. at 19), allegations like theirs, which refer vaguely to "Defendants" without specifying *which* Defendant engaged in *what* conduct, violate Rule 8 "because the allegations do not inform *each* Defendant of the particular claims against it." *Sheeran v. Blyth Shipholding S.A.*, No. CV 14-5482 (JBS/AMD), 2015 WL 9048979, at *4 (D.N.J. Dec. 16, 2015); *see also Falat v. Cty. of Hunterdon*, No. CIV.A. 12-6804, 2013 WL 1163751, at *3 (D.N.J. Mar. 19, 2013) ("Plaintiffs cannot merely state that '*Defendants* did x'—they must specifically allege *which* Defendants engaged in what wrongful conduct."). The Master Complaints fail this test as to the Pharmacies because they do not identify which claims they are bringing against the

Pharmacies,[6] or what non-conclusory allegations Plaintiffs are raising against the Pharmacies.[7] Though Plaintiffs rely on the sheer volume of the pleadings to argue that the "robust" Complaints "laboriously recount" Plaintiffs' factual allegations (Opp. at 20), Rule 8 requires and rewards fair notice, not mere length. Plaintiffs' pleadings are deficient and fail to afford the Pharmacies fair notice of the conduct in which they are alleged to have participated, and the claims asserted against them. Accordingly, they should be dismissed.

2. Plaintiffs fail to adequately plead their claims based on fraud.

The inadequacy of Plaintiffs' pleadings is exemplified by Plaintiffs' fraud-based claims. Plaintiffs offer no response to *their own allegation* that the manufacturing defendants concealed the presence of nitrosamine in valsartan.

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[6] For example, Plaintiffs' negligence-per-se claim alleges violation of various manufacturing rules, but never alleges that any Pharmacy violated such rules, nor how one could. *See, e.g.*, PIMC at 36, 40–43 (general allegations about misbranded drugs), 45–47 (general allegations about Good Manufacturing Practices), 47–48 (general allegations about drug approvals), 60, ¶ 278 (allegation of statutory violation by one manufacturer), & 77, ¶ 354 (alleging statutory violations in section addressing "all Manufacturer Defendants"); ELMC at 127–128 (alleging negligence per se based on manufacturing standards); *see also Strunk v. U.S. House of Representatives,* 68 F. App'x 233, 235 (2d Cir. 2003) (without explaining "which defendants violated which statutes," complaint did not give sufficient notice).

[7] For example, it is doubtful that the manufacturing defect claim is directed at the Pharmacies because that claim is based on "Defendants' conduct in defectively manufacturing Valsartan" (MMMC ¶ 433) and contains no allegations relating to sales. MMMC ¶¶ 431–436.

(Pharmacy Br. at 22; Opp. at 16.) With that assertion, Plaintiffs have pleaded themselves out of a fraud claim, because that allegation contradicts their allegations that the Pharmacies knew or should have known of the impurities that the manufacturers concealed.

Even apart from the concealment admission, Plaintiffs' fraud argument still fails. As Plaintiffs concede, fraud requires that any material representation or omission must be made with knowledge of its falsity. (Opp. at 83–84.) While Rule 9(b) allows knowledge of fraud to be "alleged generally," a claim that a defendant knew about fraud still must rest on factual allegations, not bare assertions. For example, the Third Circuit rejected the argument that directors must have known about fraud because of their position in a company: "A pleading of scienter sufficient to satisfy Rule 9(b) may not rest on a bare inference that a defendant 'must have had' knowledge of the facts or 'must have known' of the fraud given his or her position in the company." *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 282 (3d Cir. 2006) (some internal quotation marks omitted) (affirming dismissal of claims against directors). Yet that is exactly the argument Plaintiffs make here—that the Pharmacies must have known of drug impurities because others in the supply chain knew about the impurities. Indeed, the closest Plaintiffs come to alleging that the Pharmacies had any sort of knowledge of fraud is an indiscriminate, industry-wide allegation that "[t]he

pharmaceutical industry has been aware of the potential for the formation of nitrosamines in pharmaceutical drugs at least as far back as 2005." (PIMC ¶ 168.) But even that allegation does not address the knowledge necessary to show fraud here—whether *the Pharmacies* knew nitrosamines formed in valsartan.

The other allegations that Plaintiffs rely on to refute this pleading deficiency do not even address the issue of actual or constructive knowledge by the Pharmacies. (Opp. at 19, 90, 91, & 93 (citing allegations that NDMA causes cancer and that the Manufacturer Defendants disregarded current Good Manufacturing Practices). Even in their opposition, Plaintiffs never assert that the Pharmacies knew of the nitrosamine impurity before dispensing valsartan to patients.[8] Given Plaintiffs' failure to allege knowledge—and their admission about concealment—their fraud-based claims fail.

3. Plaintiffs have failed to state a negligence claim because they failed to allege either knowledge or a duty.

Relatedly, Plaintiffs' negligence claims fail, first, because Plaintiffs *still* have not articulated any factual basis for their assertion that the Pharmacies knew of the alleged defect and, second, because Plaintiffs' allegations that the

[8] Plaintiffs do not discuss *In re Propulsid Prods. Liab. Litig.*, MDL No. 1355, 2001 WL 1446714 (E.D. La. July 2, 2002), beyond a parenthetical—presumably because of how factually distinct it is from this litigation. There, the pharmacy defendants allegedly acted as "independent advisors" to prescribing physicians and affirmatively misrepresented the drug's side effects. *Id.* at *3. Not so here.

Pharmacies *should have* known or had some undefined duty to test to identify the defect are insufficient to save these claims.

As to actual knowledge, Plaintiffs argue that the Pharmacies were negligent in failing to take "adequate steps to detect or guard against the sale of contaminated VCDs to Plaintiffs," which in turn rests on the allegation that "the contamination certainly was known or knowable to each Defendant." (Opp. at 2.) Conclusory assertions aside, Plaintiffs have failed to plead any facts demonstrating that the Pharmacies knew or should have known about the very impurity, nitrosamine, that Plaintiffs simultaneously allege the Manufacturing Defendants hid from them. The circular nature of this argument, and of the pleadings themselves, highlights why it simply is not the case, as Plaintiffs argue, that arguments about knowledge "might be pertinent at summary judgment but [are] not here," on Defendants' Rule 12 motion. (Opp. at 3.) Plaintiffs' failure to plead a factually sufficient, plausible basis for asserting that the Pharmacies had knowledge of the impurity but continued to dispense valsartan, warrants the dismissal of such claims.

In the absence of any basis for asserting actual knowledge, Plaintiffs argue that the Pharmacies "should have known" about the contamination because of some undefined "duty to test drugs they sell" and "dut(y) to appropriately vet their generic manufacturer suppliers to ensure that they did not sell adulterated,

misbranded and/or contaminated product." (Opp. at 81.) There is *no law* that imposes such a duty on Pharmacies. And Plaintiffs cite none. Unable to identify even a single case supporting their position, Plaintiffs instead rely on a string cite of cases finding generally that a wholesaler might be negligent. (Opp. at 81–83). But none of these cases actually identifies a duty to test or relies on a pharmacy's failure to do so as the basis for liability.[9] In fact, of all the cases that Plaintiffs cite in support of their negligence claim against the Pharmacies, the only one that mentions a duty to test actually cites a number of cases *rejecting* such a duty. *O'Neill v. Standard Homeopathic Co.*, 346 F. Supp. 3d 511, 532 (S.D.N.Y. 2018) (citing five cases to show that there is no duty to test, noting that the plaintiff did not adequately allege a duty to test, and holding that the defendant retailers "cannot

[9] *Arrington v. Walgreen Co.*, 664 F. Supp. 2d 1230, 1233 (M.D. Fla. 2009) (professional negligence case involving allegation that pharmacy dispensed non-defective drug to patient despite knowing the patient was allergic to ingredient in the drug); *In re Welspun Litig.*, No. 16 CV 6792, 2019 WL 2174089, at *14, 19 (S.D.N.Y. May 20, 2019) (addressing negligent-misrepresentation claim about falsely labeled bed linens without mentioning any duty to test); *Kurtz v. Kimberly-Clark Corp.*, 321 F.R.D. 482, 534, 527, 554 (E.D.N.Y. 2017) (in a case about class certification, not dismissal, discussing a *plaintiff's* failure to "perform any objective test" and denying certification as to negligent-misrepresentation claims without mentioning any duty to test for defendants); *Fagan*, 356 F. Supp. 2d at 204 (saying nothing about a duty to test, because the product's counterfeit nature was patent: "the counterfeit lot could be determined by examining the vial label"); *Dunn v. Kanawha Cty. Bd. of Educ.*, 459 S.E.2d 151, 154–155 (W. Va. 1995) (addressing a claim against a manufacturer, not a retailer, of a pesticide and saying nothing about a duty to test); *see also In re Target Corp. Data Sec. Breach Litig.*, 66 F. Supp. 3d 1154 (D. Minn. 2014) (not mentioning any duty to test).

be held liable for a breach of an implied warranty of merchantability for a safety defect they could not have plausibly discovered").

As to the alleged duty of retailers to vet suppliers (Opp. at 37), Plaintiffs' theory fails at the outset because they never pleaded it. Plaintiffs likely did not plead such a duty because it has never before been recognized under the law. Indeed, this litigation demonstrates why there is no need for this Court to invent a duty for retailers to vet suppliers, as here the manufacturers have been identified and are actively defending this litigation. More fundamentally, those manufacturers are approved (i.e., "vetted") by FDA and subject to FDA's continuing jurisdiction and inspections and to a duty to ensure the safety and therapeutic equivalence of the generic drugs they make. The administrative scheme does not deputize pharmacies as mini-FDAs that may second guess the FDA. Further, if "[i]t is the general rule that a vendor or dealer, who is not the manufacturer, is under no obligation to test an article purchased and sold by him for the purpose of discovering latent or concealed defects," because he "may assume that the manufacturer has done his duty in properly constructing the article," *Lowe v. Am. Mach. & Foundry Co.*, 208 S.E.2d 585, 588 (Ga. Ct. App. 1974), then it should be even more true that a pharmacy providing FDA-vetted drugs from an FDA-vetted manufacturer should also be able to assume the manufacturer has done its duty.

II. Plaintiffs ignore the plain language of the Drug Supply Chain Security Act, which preempts their claims against the Pharmacies.

This Court should also dismiss all of Plaintiffs' claims because they are preempted. In just over a single page and without citing a single case, Plaintiffs offer a half-hearted rebuttal to the express preemption clause of the Drug Security Act, 21 U.S.C. § 360eee-4, providing nothing more than an unadorned "because I said so" argument. (Opp. at 47-48.) Plaintiffs aver that their claims do not involve or implicate "product tracing" and therefore are not preempted.

The Act's text, however, contradicts this claim. Specifically, the Act preempts any requirements for tracing products through the drug distribution system and expressly defines "any requirements with respect to" (1) "transaction statement[s]," (2) "verification," (3) "investigation," or (4) "recordkeeping" as "requirements for tracing products." 21 U.S.C. § 360eee-4(a). Subsection 4(e)'s savings clause simply parrots back the broad scope of product tracing by confirming that claims unrelated to "product tracing as described in subsection (a)" are not preempted. § 360eee-4(c). Plaintiffs do not explain how "product tracing"—especially as defined in the Act—means anything other than the entirety of the Act's requirements for pharmacies. In fact, they allege, albeit incorrectly, that the Pharmacies are "obligated under the Drug Supply Chain Security Act to quarantine and investigate potentially illegitimate . . . drugs." (ELMC ¶ 410.)

Despite their own allegations, Plaintiffs would have this Court believe that "product tracing" means nothing more than locating a drug within the supply chain. But the Act's product-tracing requirements cover much more. To prevent the circulation of counterfeit or misbranded drugs, the Act expressly forbids pharmacies from accepting drug shipments *unless certain criteria are met*. 21 U.S.C. § 360eee-1(d)(1)(A)(i). Pharmacies cannot accept a drug shipment unless it is accompanied by a transaction statement certifying that the manufacturer "did not knowingly ship a suspect or illegitimate product." § 360eee(27)(D). And Congress expressly included requirements about transaction statements, verification, and investigation as part of the explicit definition of what "product tracing" includes. § 360eee-4(a); *accord* § 360eee-1(g).

Accordingly, "tracing" necessarily includes a pharmacy's criteria for whether to accept a drug shipment, given the Act's inclusion of "transaction statements," "investigation," and "verification" in the preemption clause's definition of product tracing. Indeed, the very duties Plaintiffs claim the Pharmacies have breached—a duty "to appropriately vet their generic manufacturer suppliers to ensure that they did not sell adulterated, misbranded and/or contaminated product" (Opp. at 81)—are implicated by the Act's product-tracing requirements and insistence that pharmacies reject drug shipments when

the manufacturers have *not* provided the information Congress deemed appropriate.

Earlier in their brief, Plaintiffs argue that the Act requires pharmacies "not to place adulterated and/or misbranded drugs into the drug supply chain." (Opp. at 37.) The Drug Security Act does not stretch that far,[10] but Plaintiffs' argument reveals why "product tracing," as defined by the Act, necessarily includes "vetting" manufacturers. Through the Drug Security Act, Congress made the decision of what pharmacies *must* require from drug manufacturers before they may accept shipment. The very point of the Act is to protect against counterfeit or misbranded drugs, exactly what Plaintiffs allege here. But Congress also said that states could not impose *greater* requirements than what the Act requires.

Finally, Plaintiffs argue that the Pharmacies can be "found liable for violating state law product tracing requirements that parallel, and therefore do not conflict with, the" Act, which, they argue, is a question of fact. (Opp. at 48.) This argument fails for several reasons.

[10] Had Congress wanted to require more of pharmacies, it could have easily insisted that the transaction statement include more information from the manufacturer and its processes for ensuring suspect product does not enter the supply chain. But Congress did not. Congress required that pharmacies reject drugs *only* where manufacturers fail to declare that they have not *knowingly* shipped misbranded product. 21 U.S.C. § 360eee(27)(D).

First, the Plaintiffs have not pleaded it. They did not allege that the Pharmacies failed to reject drug shipments because they were unaccompanied by a transaction statement indicating that the manufacturers did not knowingly ship a misbranded drug, and further, that such a nonexistent failure caused them harm.

Second, such a requirement exists solely because of federal law, and thus any duty associated with the transaction statement would be preempted. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001) (tort claims that solely rely on federal law as source of duty are preempted). No matter the allegation, Plaintiffs cannot "navigat[e] between Scylla and Charybdis" by finding a claim "that parallel[s] federal duties but do[es] not depend solely on federal law." *Caplinger v. Medtronic, Inc.,* 784 F.3d 1335, 1340, 1343 (10th Cir. 2015) (Gorsuch, J.). Further, preemption is a question of law for this Court. *E.g.*, *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679–80 (2019).

Preemption under the Drug Security Act is precisely the "silver bullet" that knocks out all claims against the Pharmacies (*see* Opp. at 5), and Plaintiffs offer no reasoned explanation for why the Act does *not* preempt their claims.

III. Conclusion.

For all these reasons, as well as those in the Pharmacies' Opening Brief, and corresponding arguments made by the Pharmacies' co-defendants, the Pharmacies request that this Court dismiss with prejudice all of Plaintiffs' claims against them.

Dated: October 16, 2020

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CERTIFICATE OF SERVICE

I hereby certify that on this 16th day of October, 2020, I caused the foregoing Reply Memorandum of Law in Support of Rule 12 Motion to Dismiss Submitted on Behalf of all Pharmacy Defendants to be filed electronically through the CM/ECF system, which will send notice of filing to all CM/ECF participants.

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